



DEPARTMENT OF HEALTH & HUMAN SERVICES

HEH-SS 7/10/97
Public Health Service
Food and Drug Administration
CINCINNATI DISTRICT OFFICE

D1144B
1141 Central Parkway
Cincinnati, OH 45202-1097

January 29, 1997

WARNING LETTER
CIN-WL-97-5

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. David R. Self, President
Shair Laboratories, Inc.
1409 Lytle Street
Louisville, KY 40203

Re: "Revitalize Shampoo Step 1"
"Revitalize Conditioner Step 2"
"Shair Forever Shampoo"
"GENESIS Exclusive Formula Shampoo Step 1"

Dear Mr. Self:

This letter is in reference to the manufacturing and distribution of the above referenced products by your firm. The labeling for these products indicates that the products are "effective against dandruff", and aid in hair growth and/or "prevent hair loss". Based on these claims, these products are drugs (Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act)).

Three products, "Revitalize Shampoo Step 1", "Revitalize Conditioner Step 2", and "GENESIS Exclusive Formula Shampoo Step 1" all claim to "help prevent hair loss", and to be "effective against dandruff". Based on these claims, the products are drugs subject to final rules covering Hair Grower and Hair Loss Prevention Drug Products for OTC Human Use (21 CFR §310.527) and Dandruff, Seborrheic Dermatitis, and Psoriasis Drug Products (21 CFR §358.701). The "Shair Forever Shampoo" claims that it "stops excess hair loss, and stimulates dormant hair". This product is thus subject to the final rule on Hair Grower and Hair Loss Prevention Drug Products for OTC Human Use (21 CFR §310.527).

None of the products listed above meet the requirements of these final rules. Therefore, they are "new drugs" (Section 201(p) of the Act), which may not be marketed in interstate commerce unless they are subjects of approved New Drug Applications (NDA).

Further, these products are misbranded (Section 502(f)(1) and 502(f)(2) of the Act) because they fail to bear adequate directions for use and warnings required by the final rules. These products are also misbranded (Section 502(o) of the Act) because they were manufactured in an establishment not duly registered (Section 510 of the Act) and these products have not been listed with the FDA as required (Section 510(j)).

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Our investigation also documented deviations from the Current good manufacturing practice for finished pharmaceuticals regulations, Title 21 Code of Federal Regulations, Parts 210 and 211. These deviations cause your OTC drug products to be adulterated within the meaning of section 501(a)(2)(B) of the ACT.

Our investigation revealed the following:

Failure to document that each batch of your drug products is tested for conformance to final specifications prior to release for distribution.

Failure to establish and implement adequate record keeping procedures. There are no master production and control records and batch production and control records established and maintained for your drug products.

Failure to establish written procedures for production and process controls covering all aspects of the manufacturing procedures designed to assure that your drug products have the identity, strength, quality, and purity they purport or are represented to possess.

Failure to have adequate stability-indicating test procedures for your OTC drug products.

Failure to have adequate procedures for the handling of all written and oral complaints regarding your OTC drug products.

The above listed violations are not intended to be an all inclusive list of deficiencies at your firm. It is your responsibility to ensure that your labeling, including any of your catalogs, and all of your firm's products meet requirements of the Act and its implementing regulations. Federal agencies are advised on the issuance of all Warning Letters about drugs so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these violations. Failure to correct these violations may result in regulatory action without further notice. This action may include seizure and/or injunction.

Please notify this office in writing within fifteen (15) working days of receipt of this letter of the specific actions you are taking to correct these violations. Your response should describe the specific actions you will take to correct the violations. Your response should also include an explanation of each step being taken to prevent recurrence of similar violations. If corrective actions cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which corrections will be completed.

Your reply should be sent to the Food and Drug Administration, 1141 Central Parkway, Cincinnati, Ohio 45202-1097, to the attention of Evelyn D. Forney, Compliance Officer.

Sincerely,



John R. Marzilli
District Director
Cincinnati District